

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CHARLESTON DIVISION

LINDA HOWARD and JEFFREY HOWARD,

Plaintiffs,

v.

Civil Action No. 2:12-cv-04145

BOSTON SCIENTIFIC CORP.,

Defendant.

MEMORANDUM OPINION AND ORDER
(Defendant's Motion for Summary Judgment)

Pending before the court is defendant Boston Scientific Corp.'s ("BSC") Motion for Summary Judgment and Memorandum in Support Against Plaintiffs Linda Howard and Jeffrey Howard ("Motion") [Docket 46]. As set forth below, BSC's Motion is **GRANTED IN PART** with respect to the plaintiffs' claims of strict liability for manufacturing defect, strict liability for design defect, strict liability for failure to warn, negligent manufacturing, negligent failure to warn, breach of express warranty, breach of implied warranty of merchantability, and breach of implied warranty of fitness for a particular purpose. BSC's Motion is **DENIED IN PART** with respect to the plaintiffs' claims of negligent design and loss of consortium.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are approximately 75,000 cases currently pending, approximately 19,000 of which are in the Boston

Scientific Corp. MDL, MDL 2326. In an effort to efficiently and effectively manage this massive MDL, I decided to conduct pretrial discovery and motions practice on an individualized basis so that once a case is trial-ready (that is, after the court has ruled on all *Daubert* motions and summary judgment motions, among other things), it can then be promptly transferred or remanded to the appropriate district for trial. To this end, I ordered the plaintiffs and defendant to each select 50 cases, which would then become part of a “wave” of cases to be prepared for trial and, if necessary, remanded. (*See* Pretrial Order # 65, *In re Boston Scientific Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-002326, entered Dec. 19, 2013, *available at* <http://www.wvsc.uscourts.gov/MDL/boston/orders.html>). This selection process was completed twice, creating two waves of 100 cases, Wave 1 and Wave 2. The Howards’ case was selected as a Wave 2 case by the plaintiffs.

Plaintiff Linda Howard was surgically implanted with the Obtryx Transobturator Mid-Urethral Sling System (the “Obtryx”) on August 27, 2010. (Am. Short Form Compl. [Docket 10] ¶¶ 8, 10). She received the surgery at a hospital in Encinitas, California. (*Id.* ¶ 11). Her surgery was performed by Dr. Edward Cohen. (*Id.* ¶ 12). Ms. Howard claims that as a result of implantation of the Obtryx, she has experienced multiple complications. The plaintiffs bring the following claims against BSC: strict liability for manufacturing defect, design defect, and failure to warn; negligence; breaches of express and implied warranties; loss of consortium; and punitive damages. (*Id.* ¶ 13).

II. Legal Standards

A. Summary Judgment

To obtain summary judgment, the moving party must show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not “weigh the evidence and determine the truth of the matter.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242,

249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some “concrete evidence from which a reasonable juror could return a verdict” in his or her favor. *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere “scintilla of evidence” in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Dash v. Mayweather*, 731 F.3d 303, 311 (4th Cir. 2013); *Stone v. Liberty Mut. Ins. Co.*, 105 F.3d 188, 191 (4th Cir. 1997).

B. Choice of Law

Under 28 U.S.C. § 1407, this court has authority to rule on pretrial motions in MDL cases such as this. The choice of law for these pretrial motions depends on whether they involve federal or state law. “When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. When considering questions of state law, however, the transferee court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation.” *In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996) (internal citations omitted). In cases based on diversity jurisdiction, the choice-of-law rules to be used are those of the states where the actions were originally filed. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir.

1996) (“Where a transferee court presides over several diversity actions consolidated under the multidistrict rules, the choice of law rules of each jurisdiction in which the transferred actions were originally filed must be applied.”); *In re Air Crash Disaster Near Chi., Ill.*, 644 F.2d 594, 610 (7th Cir. 1981); *In re Digitek Prods. Liab. Litig.*, No. 2:08-md-01968, 2010 WL 2102330, at *7 (S.D. W. Va. May 25, 2010).

If a plaintiff files her claim directly into the MDL in the Southern District of West Virginia, however, as the Howards did in this case, I consult the choice-of-law rules of the state in which the implantation surgery took place. *See Sanchez v. Boston Scientific Corp.*, 2:12-cv-05762, 2014 WL 202787, at *4 (S.D. W. Va. Jan. 17, 2014) (“For cases that originate elsewhere and are directly filed into the MDL, I will follow the better-reasoned authority that applies the choice-of-law rules of the originating jurisdiction, which in our case is the state in which the plaintiff was implanted with the product.”). Ms. Howard received her implantation surgery in California. (Am. Short Form Compl. [Docket 10], ¶ 11). Thus, the choice-of-law principles of California guide this court’s choice-of-law analysis.

These principles compel application of California law. In tort actions, California follows the “governmental interest” approach in determining choice of law questions. *Kasel v. Remington Arms Co.*, 101 Cal. Rptr. 314, 327 (Ct. App. 1972). First, the court should determine whether the laws of each potential jurisdiction actually differ with regard to the particular issue in question. *Kearney v. Salomon Smith Barney, Inc.*, 137 P.3d 914, 922 (Cal. 2006). Second, where the laws of each jurisdiction differ, the court must determine whether a “true” conflict exists by determining whether each state has an interest in applying its law in this case. *Id.* Finally, if a true conflict exists, the court will determine “which state’s interest would be more impaired if its policy were subordinated to the policy of the other state” and apply that state’s law. *Id.* (quoting *Bernhard v.*

Harrah's Club, 546 P.2d 719, 723 (Cal. 1976), *abrogated on other grounds* by Cal. Civ. Code § 1714(b)). California law will presumptively apply unless there are compelling reasons to do otherwise. *Browne v. McDonnell Douglas Corp.*, 504 F. Supp. 514, 517 (N.D. Cal. 1980) (citing *Kasel*, 101 Cal. Rptr. at 327).

Here, the plaintiffs are California residents. (Am. Short Form Compl. [Docket 10] ¶ 4). In addition, Ms. Howard was implanted with the device and allegedly suffered injury in California. (*Id.* ¶¶ 11, 13). No other states appear to have an interest in having their law applied. Thus, I apply California's substantive law to this case.

III. Analysis

A. Strict Liability

1. Manufacturing Defect

A product suffers from a manufacturing defect when it “differs from the manufacturer’s intended result or from other ostensibly identical units of the same product line.” *Barker v. Lull Eng’g Co.*, 573 P.2d 443, 454 (Cal. 1978). The “[f]ocus is on whether the particular product involved in the incident was manufactured in conformity with the manufacturer’s design.” *In re Coordinated Latex Glove Litig.*, 121 Cal. Rptr. 2d 301, 315 (Ct. App. 2002), *as modified on denial of reh’g* (July 15, 2002).

The plaintiffs have presented no evidence showing the existence of a manufacturing defect in the particular product implanted in Ms. Howard. Therefore, BSC’s Motion on the plaintiffs’ claim of strict liability for manufacturing defect is **GRANTED**.

2. Design Defect

A design defect exists when a “product is built in accordance with its intended specifications, but the design itself is inherently defective.” *McCabe v. Am. Honda Motor Co.*, 123 Cal. Rptr. 2d 303, 309 (Ct. App. 2002).

California does not recognize strict liability for defective design of implantable medical devices. *See Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763, 772 (Ct. App. 1996) (“In the context of medical devices, design defects must be pursued under a negligence theory.”); *Hufft v. Horowitz*, 5 Cal. Rptr. 2d 377, 382 (Ct. App. 1992) (citing *Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988)) (“*Brown’s* exception to strict liability for design defects applies to manufacturers of implanted medical devices” (restyled)), *op. modified* (Mar. 17, 1992).

Therefore, BSC’s Motion on the plaintiffs’ claim of strict liability for design defect is **GRANTED**.

3. Failure to Warn

A product may be “flawlessly designed and produced” and yet “possess such risks to the user without a suitable warning that it becomes ‘defective’ simply by the absence of a warning.” *Cavers v. Cushman Motor Sales, Inc.*, 157 Cal. Rptr. 142, 147 (Ct. App. 1979). Such warnings fall into two categories: a warning on proper use of a product and a warning of risks that may follow the proper use of the product. *Finn v. G. D. Searle & Co.*, 677 P.2d 1147, 1152 (Cal. 1984). The second type of warning is most salient in the medical context.

In order to establish a claim for failure to warn, whether in strict liability or in negligence, a plaintiff must prove that the defendant’s warnings were inadequate and that the inadequate warnings were a substantial factor in causing the plaintiff’s harm. *See Anderson v. Owens-Corning Fiberglas Corp.*, 810 P.2d 549, 558 (Cal. 1991) (stating that both negligence and strict liability require showing that warnings were inadequate); *Rosa v. City of Seaside*, 675 F. Supp. 2d 1006, 1011 (N.D. Cal. 2009) (listing elements of negligence and strict liability failure-to-warn claims).

The learned intermediary doctrine is part and parcel of a failure-to-warn analysis in California. Under the learned intermediary doctrine, manufacturers of prescription drugs and medical devices satisfy their duty to warn if they provide adequate warnings to prescribing

physicians, rather than patients. *See Carlin v. Superior Court*, 920 P.2d 1347, 1354 (Cal. 1996) (“[I]n the case of prescription drugs, the duty to warn runs *to the physician*, not to the patient.”); *Brown v. Superior Court*, 751 P.2d 470, 477 n.9 (Cal. 1988) (“It is well established that a manufacturer fulfills its duty to warn if it provides adequate warning to the physician.”).

In order to establish causation under the learned intermediary doctrine, a plaintiff must demonstrate that the prescribing physician would have acted differently had he or she received adequate warnings. *See Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 995 (C.D. Cal. 2001) (“Pfizer may prevail in its motion for summary judgment if Ms. Motus has failed to adduce evidence that Dr. Trostler would have acted differently had Pfizer provided an adequate warning”), *aff’d sub nom. Motus v. Pfizer Inc. (Roerig Div.)*, 358 F.3d 659 (9th Cir. 2004); *Georges v. Novartis Pharm. Corp.*, 988 F. Supp. 2d 1152, 1157–58 (C.D. Cal. 2013) (holding that plaintiff must prove her injuries “resulted from Defendant’s inadequate warnings” and upholding jury verdict for plaintiff where treating physician “testified that he changed his treatment practices once he was aware of the [product] risk”); *Plummer v. Lederle Labs., Div. of Am. Cyanamid Co.*, 819 F.2d 349, 358 (2d Cir. 1987) (applying California law) (no proximate causation where plaintiff “failed to prove that a proper warning would have altered the doctor’s conduct”). Thus, if a doctor did not read the warning, or if a doctor read but did not rely on the warning, then the chain of causation is broken and a plaintiff cannot establish proximate causation. *See Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 308–09 (Ct. App. 2008) (causation is jury question where prescribing doctor “probably read” manufacturer’s warnings); *see also Latiolais v. Merck & Co., Inc.*, 302 F. App’x 756, 757 (9th Cir. 2008) (no causation where drug warnings “did not play a role in [the physician’s] decision to prescribe” the drug).

Here, there is no evidence that Dr. Cohen, the implanting physician, read the Obtryx's Directions for Use ("DFU"). Thus, no amount of additional warnings in the DFU would have changed Dr. Cohen's course of action. *See Conte*, 85 Cal. Rptr. 3d at 308–09. Furthermore, even assuming Dr. Cohen had read the DFU, there is no evidence that he would have taken a different course of action had he been given an adequate warning. Therefore, the plaintiffs cannot establish proximate causation. *See Motus*, 196 F. Supp. 2d at 995. Accordingly, BSC's Motion on the plaintiffs' claim of strict liability for failure to warn is **GRANTED**.

B. Negligence

In a negligence suit, the plaintiff must establish (1) duty; (2) breach of duty; (3) causation; and (4) damages. *Ann M. v. Pac. Plaza Shopping Ctr.*, 863 P.2d 207, 211 (Cal. 1993), *disapproved of on other grounds by Reid v. Google, Inc.*, 235 P.3d 988 (Cal. 2010).

1. Negligent Manufacturing

As explained earlier, the plaintiffs have presented no evidence showing the existence of a manufacturing defect—to evidence a breach of duty—in the particular product implanted in Ms. Howard. *See supra* Part III.A.1. Therefore, BSC's Motion on the plaintiffs' claim of negligent manufacturing is **GRANTED**.

2. Negligent Design

Although California does not recognize strict liability for defective design, the plaintiffs may still pursue a claim of negligent design. BSC's argument to the contrary is unavailing. My analysis in *Sanchez v. Boston Scientific Corp.* on this point remains instructive:

Several California appellate courts have made clear that [*Brown v. Superior Court*, 751 P.2d 470, 483 (Cal. 1988),] did not abolish ordinary negligence actions against drug manufacturers. *See, e.g., Garrett v. Howmedica Osteonics Corp.*, 153 Cal. Rptr. 3d 693, 699 (Ct. App. 2013) ("The California Supreme Court in *Brown* . . . held that a manufacturer of prescription drugs cannot be strictly liable for a design defect and that the appropriate test for determining a prescription drug manufacturer's liability for a design defect involves an application of the ordinary

negligence standard.”); [*Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763, 772 (Ct. App. 1996)]; [*Hufft v. Horowitz*, 5 Cal. Rptr. 2d 377, 382 (Ct. App. 1992)] (“*Brown* does not exempt a drug manufacturer from . . . liability for negligence or failure to warn of known or reasonably knowable side effects.”). Several federal courts applying California law also agree that manufacturers of medical devices may be liable for ordinary negligence for the design of their products. *See, e.g., Dilley v. C.R. Bard, Inc.*, No. 2:14-cv-01795-ODW, 2014 WL 2115233, at *3–4 (C.D. Cal. May 21, 2014) (granting plaintiff leave to amend complaint to add design defect negligence claim); *Tucker v. Wright Med. Tech., Inc.*, No. 11-cv-03086-YGR, 2013 WL 1149717, at *7–10 (N.D. Cal. Mar. 19, 2013) (denying device manufacturer’s motion for summary judgment on negligent design claim).

38 F. Supp. 3d 727, 737 (S.D. W. Va. 2014).

BSC has presented no other argument on negligent design. Thus, BSC has failed to meet its burden of showing the absence of a genuine dispute as to any material fact. *See Fed. R. Civ. P. 56(a); Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970), *superseded on other grounds by Celotex Corp. v. Catrett*, 477 U.S. 317 (1986). Therefore, BSC’s Motion on the plaintiffs’ claim of negligent design is **DENIED**.

3. Negligent Failure to Warn

As explained earlier, there is no evidence that Dr. Cohen read the DFU. Thus, no amount of additional warnings would have changed Dr. Cohen’s course of action. *See supra* Part III.A.3. And even assuming Dr. Cohen had read the DFU, there is no evidence that he would have taken a different course of action had he been given an adequate warning. Thus, the plaintiffs cannot establish proximate causation. *See id.* Therefore, BSC’s Motion on the plaintiffs’ claim of negligent failure to warn is **GRANTED**.

C. Breach of Express Warranty

“Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.” Cal. Com. Code § 2313(1)(a). A plaintiff need not prove

that she relied on any statements made by manufacturer. *Keith v. Buchanan*, 220 Cal. Rptr. 392, 397 (Ct. App. 1985). Instead, a rebuttable presumption arises that such statements have been “w[oven] . . . into the fabric of the agreement,” and “any fact which is to take such affirmations, once made, out of the agreement requires clear affirmative proof.” Cal. Com. Code § 2313 cmt. para. 3; *accord Keith*, 220 Cal. Rptr. at 397. “If, however, the resulting bargain does not rest at all on the representations of the seller, those representations cannot be considered as becoming any part of the ‘basis of the bargain.’” *Keith*, 220 Cal. Rptr. at 397 (citation omitted). Furthermore, in an action for breach of express warranty, privity is not required, *Rodrigues v. Campbell Indus.*, 151 Cal. Rptr. 90, 93 (Ct. App. 1978), nor is notice required, *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897, 900 (Cal. 1963). In addition, the learned intermediary doctrine applies to breach of warranty claims, and thus, “for purposes of liability for breach of warranty, ordinarily it is the prescribing doctor who in reality stands in the shoes of the ordinary consumer.” *Carlin v. Superior Court*, 920 P.2d 1347, 1355 (Cal. 1996) (internal quotation marks omitted).

Here, the plaintiff has not presented any facts indicating that the resulting bargain rested on representations from BSC, and thus, it cannot be said that those representations formed any “part of the basis of the bargain.” *See* Cal. Com. Code § 2313(1)(a); *Keith*, 220 Cal. Rptr. at 397. Therefore, BSC’s Motion on the plaintiffs’ claim of breach of express warranty is **GRANTED**.

D. Breach of Implied Warranties

California law provides for two types of implied warranties: (1) the implied warranty of merchantability and (2) the implied warranty of fitness for a particular purpose. *See* Cal. Com. Code §§ 2314, 2315.

In an action for breach of implied warranty, a plaintiff must be in privity with the defendant. *Rodrigues*, 151 Cal. Rptr. at 93. One exception to the privity requirement has been for claims involving food manufacturers. *Evraets v. Intermedics Intraocular, Inc.*, 34 Cal. Rptr. 2d 852, 857

(Ct. App. 1994); *Klein v. Duchess Sandwich Co.*, 93 P.2d 799, 801 (Cal. 1939). Although this exception has been extended to drugs, *Gottsdanker v. Cutter Labs.*, 6 Cal. Rptr. 320, 323 (Ct. App. 1960), vaccines, *id.*, and pesticides, *Arnold v. Dow Chem. Co.*, 110 Cal. Rptr. 2d 722, 739–40 (Ct. App. 2001), it has not been extended to medical devices, *see Evraets*, 34 Cal. Rptr. 2d at 857 (sustaining demurrer to claim for breach of implied warranty on intraocular lens for lack of privity); *see also Blanco v. Baxter Healthcare Corp.*, 70 Cal. Rptr. 3d 566, 582 (Ct. App. 2008) (heart valve); *Quatela v. Stryker Corp.*, 820 F. Supp. 2d 1045, 1048 (N.D. Cal. 2010) (pain pump).

Here, the plaintiffs have not presented any evidence that they are in privity with BSC. Therefore, BSC's Motion on the plaintiffs' claims of breach of implied warranty of merchantability and breach of implied warranty of fitness for a particular purpose is **GRANTED**.

E. Loss of Consortium

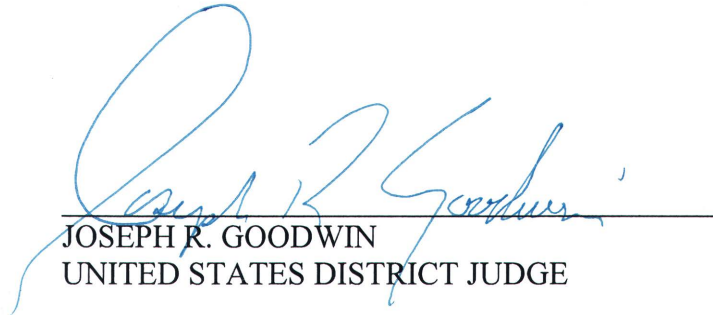
"A cause of action for loss of consortium is, by its nature, dependent on the existence of a cause of action for tortious injury to a spouse." *Hahn v. Mirda*, 54 Cal. Rptr. 3d 527, 531 (Ct. App. 2007). Because at least one of Ms. Howard's claims survives, Mr. Howard's claim of loss of consortium also survives. Therefore, BSC's Motion on the plaintiffs' claim of loss of consortium is **DENIED**.

IV. Conclusion

For the reasons discussed above, it is **ORDERED** that BSC's Motion [Docket 46] be **GRANTED IN PART** with respect to the plaintiffs' claims of strict liability for manufacturing defect, strict liability for design defect, strict liability for failure to warn, negligent manufacturing, negligent failure to warn, breach of express warranty, breach of implied warranty of merchantability, and breach of implied warranty of fitness for a particular purpose, and **DENIED IN PART** with respect to the plaintiffs' claims of negligent design and loss of consortium.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: April 11, 2016



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE